

## Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

### § 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart.

(b) The Deputy Commissioner and the Associate Commissioner for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs.

(c) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

- (1) Deputy Commissioner.
- (2) Associate Commissioner for Regulatory Affairs.
- (3) Associate Commissioner for Management and Operations.

For a planned period of absence, the Commissioner may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him as “acting” or unless not legally permissible.

(e) The Deputy Commissioner for Operations is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and may be closed to the public in accordance with § 5.10(a)(18).

(f)(1) The Deputy Commissioner for Policy and the Associate Commissioner for Policy Coordination are authorized to perform any of the functions of the Commissioner of Food and Drugs with respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration.

(2) The Deputy Commissioner for Policy is authorized to issue responses to the following matters under part 10 of this chapter as follows:

(i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19;

(ii) Citizen petitions under § 10.30;

(iii) Petitions for reconsideration under § 10.33;

(iv) Petitions for stay under § 10.35; or

(v) Requests for advisory opinions under § 10.85.

(3) With respect to any matter delegated to the Deputy Commissioner for Policy under this paragraph, the Deputy Commissioner for Policy is authorized to perform the functions of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 and of the Deputy Commissioner under § 10.206 (g) and (h) of this chapter.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices:

- (1) Deputy Commissioner for Operations.
- (2) Deputy Commissioner for Policy.
- (3) Deputy Commissioner for External Affairs.
- (4) Deputy Commissioner for Management and Systems.

(h) The Chief Mediator and Ombudsman is designated as User Fee Waiver Officer and is authorized to perform all of the functions of the Commissioner under the Prescription Drug User Fee Act of 1992 (21 U.S.C. 379h(d)), as amended hereafter, relating to waiver or reduction of user fees. The User Fee Waiver Officer's authority may be redelegated to the Deputy, Chief Mediator and Ombudsman, without further redelegation. The Deputy Commissioner for Operations is designated as User Fee Appeals Officer and authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters.

(i) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983; 56 FR 36001, July 30, 1991; 57 FR 12875, Apr. 14, 1992; 58 FR 17095, Apr. 1, 1993; 59 FR 14549, Mar. 29, 1994; 61 FR 2414, Jan. 26, 1996]

### § 5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period